Reference number(s)
2139-A

SPECIALTY GUIDELINE MANAGEMENT

PEGASYS (peginterferon alfa-2a)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Chronic Hepatitis C
   Pegasys, as part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs, is indicated for the treatment of adults with chronic hepatitis C (CHC) with compensated liver disease. Pegasys in combination with ribavirin is indicated for treatment of pediatric patients 5 years of age and older with CHC and compensated liver disease. Pegasys monotherapy is only indicated for the treatment of patients with CHC with compensated liver disease if there are contraindications or significant intolerance to other HCV antiviral drugs.
2. Chronic Hepatitis B
   Pegasys is indicated for the treatment of adult patients with HBeAg-positive and HBeAg-negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation. Pegasys is indicated for the treatment of HBeAG-positive CHB in non-cirrhotic pediatric patients 3 years of age and older with evidence of viral replication and elevations in serum alanine aminotransferase (ALT).

B. Compendial Uses
1. Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis)
2. Systemic mastocytosis
3. Adult T-Cell Leukemia/Lymphoma
4. Mycosis Fungoides/Sezary Syndrome
5. Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders
6. Hairy cell leukemia
7. Erdheim-Chester disease
8. Chronic Myeloid Leukemia

All other indications are considered experimental/investigational and not medically necessary.

II. INITIAL CRITERIA FOR APPROVAL

A. Chronic hepatitis C virus (HCV) infection
Refer to the SGM of requested regimen for the specific criteria for approval and approval durations.

B. Chronic hepatitis B virus (HBV) infection (including HDV coinfection)
Authorization of up to 48 weeks total may be granted for the treatment of chronic HBV infection, including HDV coinfection.

C. Myeloproliferative neoplasm
Authorization of 12 months may be granted for the treatment of myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis).

D. Systemic mastocytosis

Authorization of 12 months may be granted for the treatment of systemic mastocytosis.

E. Adult T-Cell Leukemia/Lymphoma
Authorization of 12 months may be granted for the treatment of adult T-cell leukemia/lymphoma.

F. Mycosis Fungoides/Sezary Syndrome
Authorization of 12 months may be granted for the treatment of Mycosis Fungoides/Sezary syndrome.

G. Primary Cutaneous CD30+ T-cell Lymphoproliferative Disorders
Authorization of 12 months may be granted for the treatment of primary cutaneous CD30+ T-cell lymphoproliferative disorders.

H. Hairy cell leukemia
Authorization of 12 months may be granted for the treatment of hairy cell leukemia.

I. Erdheim-Chester disease
Authorization of 12 months may be granted for the treatment of Erdheim-Chester disease.

J. Chronic Myeloid Leukemia
Authorization of 12 months may be granted for the treatment of chronic myeloid leukemia in pregnancy.

III. CONTINUATION OF THERAPY

A. Myeloproliferative neoplasm
Authorization of 12 months may be granted if the patient is experiencing benefit from therapy as evidenced by improvement in symptoms and/or disease markers (e.g., morphological response, reduction or stabilization in spleen size, improvement of thrombocytosis/leukocytosis, etc.)

B. Systemic mastocytosis
Authorization of 12 months may be granted if the patient is experiencing benefit from therapy as evidenced by improvement in symptoms and/or disease markers (e.g., reduction in serum and urine metabolites of mast cell activation, improvement in cutaneous lesions, skeletal disease, bone marrow mast cell burden, etc.)

C. All other indications
Authorization of 12 months may be granted for continued treatment in patients requesting reauthorization for all other indications in Section II, not previously listed, when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Pegasys [package insert]. South San Francisco, CA: Genentech, Inc; March 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 7, 2022.
3. Olysio [package insert]. Titusville, NJ: Janssen Products, LP; November 2017.
4. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
5. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made October 5, 2021. Accessed March 7, 2022.
6. Terrault NA, Bzowej NH, Chang KM, et al. AASLD guidelines for treatment of chronic hepatitis B. *Hepatology*. 2016;63(1):261-283.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Myeloproliferative Neoplasms (Version 1.2022). http://www.nccn.org. Accessed March 7, 2022.

8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Systemic Mastocytosis (Version 3.2021). http://www.nccn.org. Accessed March 7, 2022.